REMARKS/ARGUMENTS

Claims 1, 2, 9, 22 and 26 have been amended. Claims 5-8, 10-21, and 23-25, drawn to non-elected subject matter, have been cancelled without prejudice or disclaimer. Applicants respectfully reserve the right to pursue the subject matter of these claims in other (e.g. related) applications. Claims 27 and 28 have been added. Claims 1-4, 9, 22, and 26-28 remain pending upon entry of this amendment.

Claims 1 and 22 have been amended to delete the term "deduced" to which the Examiner has objected.

Claim 2 has been amended solely to be rewritten into independent form. Thus, support for this amendment can be found in originally filed claims 1 and 2. Claim 9 has also been amended to be rewritten into independent form. Support for this amendment can be found in originally filed claims 1 and 5-8. Claim 26 has also been amended to be rewritten into independent form. Support for this amendment can be found in originally filed claims 22 and 23-25.

No new matter has been added by way of these amendments.

Claim Objections

Claim 2 has been objected to as being of improper dependent form for failure to further limit the subject matter of the previous claim. At the outset, Applicants respectfully point out that amended claim 2 actually does further limit the subject matter recited in claim 1, from

which it originally depended. In particular, claim 1 specifies a chemokine that may contain any one or more of the amino acid sequences set forth in SEQ ID NO: 3, 4 or 5. By contrast, the chemokine recited in claim 2, contains all the amino acid sequences in SEQ ID NOS: 3, 4 and 5.

Nevertheless, in order to be fully responsive to the Examiner's rejection and to expedite an allowance of the pending claim, Applicants have amended claim 2 so that it is now in independent form. Thus, it is believed that this objection has been obviated and Applicants respectfully request its withdrawal.

Claims 9 and 26 have been objected to because they depend from claims that have been withdrawn from consideration. Claims 9 and 26 have been amended to be rewritten into independent form. Thus, it is believed that this objection has been obviated and Applicants respectfully request its withdrawal.

Rejections under 35 U.S.C. § 112, second paragraph-indefiniteness

Claims 1-4, 9, 22 and 26 have been rejected for alleged indefiniteness because of the term "deduced" in claims 1 and 22. Specifically, the Examiner alleges that that the claims fail to recite what parameters are necessary for the deduction of the molecular weight or isoionic points.

In response, Applicants respectfully point out that the word "deduced" has been deleted from the claims as amended herein. Hence, for example, the pending claims specify a

chemokine having a molecular weight from about 12 to about 14 kD, rather than having a "deduced" molecular weight. Thus, it is believed that this rejection has been obviated and Applicants respectfully request its withdrawal.

Rejections under 35 U.S.C. § 112, first paragraph- enablement

Claims 1-4, 9, 22 and 26 have been rejected for failure to fulfill the enablement requirement. In particular, the Examiner argues that the application is not enabling for treating "breast diseases."

In view of the absence of any evidence provided by the Examiner that the claimed method of treating will not work for any breast disease, it is believed that the Examiner imposes an overly high and burdensome duty on applicants, one not required by Section 112 or by the case law[1]. As stated in MPEP § 2164.04 (emphasis added):

> In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)

Thus, according to the current law and patent practice, the specification can permit some inferences to be drawn by those skilled in the art, and still comply with the enablement and written description requirements. In other words, there is no requirement that the claims be restricted to the working examples. Section 2164.03 of MPEP recites:

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[1] *See*, in particular, *In re Wands*, 858 F.2d 731-40, 8 USPQ2d at 1400-07 (Fed. Cir. 1988)

> the scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required (*In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir., 1991); *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971))

As further stated in section 2164.08 of MPEP:

> claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for non-inclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious (*In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970))... When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification.

See also *Application of Angstadt* (537 F.2d 498, 502-503, 190 USPQ 214, 218 [Cust. & Pat.App., 1976]) stating that applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art." Similarly, in *In re Rasmussen*, court stated that "a claim may be broader than the specific embodiment disclosed in a specification" (650 F.2d 1212, 1215, 211 USPQ 323, 326 [Cust. & Pat.App., 1981]). Finally, in *In re Goffe* (542 F.2d 564, 567, 191 USPQ 429, 431 [CCPA 1976]), the court stated:

> To provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

Moreover, and contrary to what is stated in the Office Action, this application actually describes and enables methods for treating a large number of different breast diseases,

including not only breast cancer but also benign cystitis, benign hyperplasia, inflammation of the mammary gland, and mammary gland infections, See, for example, the specification as filed at page 5, lines 6-9; and at page 8, lines 9-12.

The Examiner has also rejected claims 1-4, 9, 22 and 26 for failure to fulfill the enablement requirement because the specification allegedly fails to enable the claimed methods for the treatment of any breast disease, including breast cancer.

In response, Applicants respectfully submit that the Office Action fails to establish a prima facie case for enablement and that the claim rejection therefore should also be withdrawn. In particular MPEP § 2164.04 states:

> In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support... *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.
>
> According to *In re Bowen*, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), the minimal requirement is for the examiner to give reasons for the

> uncertainty of the enablement. This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments. See also *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995)...
>
> ... the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. See MPEP §2164.06(a)(a). References should be supplied if possible to support a prima facie case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required.

Applicants submit that the Examiner has failed to provide any reference to support the enablement rejection and has provided only faulty technical reasoning. For example, the Examiner states (at page 4 of the Office Action):

> There is no evidence that the disclosed chemokines are cellular markers for any disease of the breast, because the only data provided in the specification concerns measurement of chemokine levels in blood samples of breast cancer patients, indicating that the disclosed chemokines are secreted and do not remain with the breast tissue.

However, Applicants respectfully submit that the Examiner is actually making her own incorrect conclusions. For instance, as Example 1 of the specification demonstrates, the disclosed chemokines were cloned, via suppressive subtractive hybridization, by virtue of their being specifically expressed in human breast tissue. Example 16 of the specification then demonstrates that the disclosed chemokines are found in the sera of individuals with breast cancer, but not in normal individuals or in individuals with lung, prostrate, ovarian, or colon

cancer or lymphoma. Thus, the Examiner is simply incorrect when stating that there is no evidence linking the disclosed chemokines to diseases of the breast.

In conclusion, the claimed methods of treating breast disease are enabled by the present specification. In addition, the Examiner has failed to meet the burden of establishing a prima facie case of non-enablement and to shift the burden to the applicants. Accordingly, Applicants respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. § 112, first paragraph- written description

Claims 1, 2, 4, 9, 22 and 26 have also been rejected under the "written description" requirement of 35 U.S.C. § 112, first paragraph. In particular the Examiner argues that this application does not adequately describe the full genus of polypeptides comprising the partial chemokine amino acid sequences set forth in SEQ ID NOS: 3, 4 and 5.

Applicants respectfully disagree and submit that the pending claims do indeed comply with the written description requirement of 35 U.S.C. § 112, first paragraph. In particular, the amended claims specify methods that involve detecting the expression of a chemokine having at least the partial amino acid sequence(s) of SEQ ID NOS: 3, 4 and/or 5. Applicants respectfully point out that the term "chemokine" is well known in the art. In particular, chemokines are both known in the art and defined in the present application as "proteins which are proinflammatory cytokines that are chemoattractants and activators of specific types of leukocytes." See, in particular, page 5 at lines 31-33 of the application as filed. See, also,

U.S. Patent No. 5,688,927; and Baggiolini et al., Advances in Immunology, 55:97-179 (1994), both of which are cited in the application and incorporated therein by reference.

Hence, the term chemokine has both a structural and a functional component. Where a claim provides "a precise definition, such as by structure, formula, and chemical name of the claimed subject matter sufficient to distinguish it from other materials" that claim is considered to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. *See, Regents of the University of California v. Eli Lilly & Co.*. 119 F.2d. 1559, 1568, 43 USPQ2d 1398, 1405 (citing *Fiers v. Revel,* 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); *In re Smythe,* 480 F.2d 1376, 1383, 178 USPQ 279, 284-285 (CCPA 1973).

For these reasons, Applicants submit that the rejections under the written description requirement of 35 U.S.C. § 112, first paragraph, should be withdrawn.

Sequence Listing

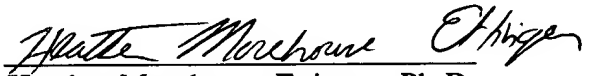
Applicants note that the STIC properly corrected the CRF for field 212 of SEQ ID NO: 7 from "NA" to "DNA." Applicants acknowledge entry of the CRF of the Substitute Sequence Listing filed on June 12, 2001.

Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

By: 
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